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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,812	12/14/2004	Harald Breivik	10260.0006-00000	8613

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EXAMINER	
CARR, DEBORAH D	

ART UNIT	PAPER NUMBER
1621	

MAIL DATE	DELIVERY MODE
01/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,812	BREIVIK ET AL.	
	Examiner	Art Unit	
	DEBORAH D. CARR	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32, 34-35,38,42-43, 45-50, 59-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *47-50 and 59* is/are allowed.

6)☒ Claim(s) *32 34-35 38 42-43 45-46 60-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 16 September 2008 have been fully considered but they are not persuasive. The rejection of claims 32-39, 42-50, 59-61 under 35 USC§112, 1st paragraph is maintained, as are the rejections of claims 32-35, 38-39, 42-50, 59-64 under 35 USC§102(b).

2. The rejection of claims 47-50 & 59 has been withdrawn.

3. Claims 33, 39, 44 have been canceled and claims 62-64 have been added.

4. Claims 32-35, 38-39, 42-50 and 59-64 are pending.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 32, 34-35, 38, 42-43, 45-50 and 59-64 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues the specification as originally filed is in compliance with the written description requirement since only requires that the specification disclose information

sufficient to show that the inventor possessed the invention at the time of the original disclosure.

As stated previously, being in possession of the invention is not in question but how to use the invention. As shown supra:

> a written description of the invention, and of the manner and process of making and **using it**, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and **use the same** and shall set forth the best mode contemplated by the inventor of carrying out his invention

The written description for the "pharmaceutically effective concentration to therapeutically treat hypertriglyceridaemia" is not present. Applicant" statement that "treatment dosages are not claimed" is questionable since the EPA/DHA esters are administered in a "pharmaceutically effective concentration to therapeutically treat hypertriglyceridaemia" which is basically a dosage.

As stated in the previous office action, applicant's arguments regarding the amounts given for various pollutants such as PCDD, PCDF, & TE PCB not being disclosed in the specification, the argument has no merit.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 32, 34-35, 38, 42-43, 45-46, 60-64 rejected under 35 U.S.C. 102(b) as being clearly anticipated by EPAX Product Specifications for EPAX 4020EE or 5500EE or 6000EE or 6010EE.

Applicant argues the product specification for EPAX does not disclose the concentration of brominated flame retardants as measured by the concentration of BDE 47. In addition, the claims recite a pharmaceutical composition that is not a health supplement which excludes EPAX because it is a health supplement.

According to the MPEP section 2107.1 pages 2100-26 it is stated that:

> The Federal Circuit has reiterated that therapeutic utility sufficient under the patent laws is not to be confused with the requirements of the FDA with regard to safety and efficacy of drugs to marketed in the United States.
> FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws. Scott [v. Finney], 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 [(Fed.Cir. 1994)].
>
> > Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

The fact that the FDA has made certain determinations regarding health supplements has no weight regarding the patentability of the instant invention. As shown in the literature for EPAX, it is made from carefully selected marine oils therefore it is unclear how applicants can make the statement that EPAX products do not comprise marine oil.

Additionally, EPAX clearly states that it's purification process reduces the amount of impurities including brominated flame retardants.

In response to applicant's argument that "wherein said pharmaceutical composition is not a health supplement", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The established definition of a "pharmaceutical composition" is any use, other than food, wherein a substance is used on or in the body to prevent, diagnose, alleviate, treat, or cure a disease in humans or animals.

EPAX states these oil form part of the health food products. The term "health food" is a non-medical term defined by the lay public as a food that has little or no preservatives, which has not undergone major processing, enrichment or refinement and which may be grown without pesticides. (From Segen, The Dictionary of Modern Medicine, 1992) If one were to go by this definition then the product produced by EPAX would not apply since it undergoes major purification processing.

Also, while EPAX can be used in food products duce to its purity, the marine oil itself can be administered in capsule form which is not traditionally considered a food.

Allowable Subject Matter

9. Claims 47-50, 59 are allowed.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH D. CARR whose telephone number is (571)272-0637. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on

access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah D Carr/
Primary Examiner
Art Unit 1621

Ddc